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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/124,280 07/29/98 PORRO M 576008

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EXAMINER

MINNIFIELD, N

ART UNIT

PAPER NUMBER

1645

10

DATE MAILED:

11/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/124,280

Applicant

PORRO

Examiner
N. M. Minnifield

Group Art Unit
1645



☒ Responsive to communication(s) filed on Aug 22, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-17 and 19-56 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 and 19-56 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment filed August 22, 2000 is acknowledged and has been entered. Claim 18 is canceled. Claims 6-17 and 19-51 have been amended. New claims 55 and 56 have been added. Claims 1-17 and 19-56 are now pending in the present application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 9, 11, 17 and 19-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and indefinite in that the claims refer to specific amino acid sequences, however the sequences do not conform to the limitations set forth in the parent claim. For example, claim 1 recites a peptide $(A)_n$, $(AB)_m$, $(ABC)_p$. The peptide set forth in claim 9 does not conform to the formula, claim 11 does not conform to one of these formulas. Applicant should insure that all sequences conform to the formulas set forth in parent claim 1. Further, do the amino acid sequences of the

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peptide have to conform to all three of these formulas or conform to just one of these formulas?

It is noted that this rejection has been maintained as Applicant has not responded to this rejection.

4. The rejection of claims 1-17, 19-34 and 51 under 35 U.S.C. 102(b) as being anticipated by Porro is maintained.

Applicant's arguments filed August 22, 2000 have been fully considered but they are not persuasive. Applicant's arguments have been addressed previously. Further, the claims do not recite "stoichiometric excess of peptide relative to the lipid moiety". However, the Examiner is not suggesting addition of this limitation to the claims.

5. The rejection of claims 1-17 and 19-56 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the LPS (from *S. Typhi*) and peptide, does not reasonably provide enablement for the use of any LPS and peptide as a vaccine preparation for preventing gram-negative infections and the effects of endotoxins is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

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The claims are directed to a vaccine for preventing gram negative infections and the effects of endotoxins which comprises a complex of LPS and a peptide or LPS in conjugate form with a peptide. Dependent claims set forth that the LPS could be obtained from *H. influenzae*, *N. meningitidis*, *S. typhi*.

Applicants' arguments have been considered however they are not deemed persuasive. Applicant asserts that the specification discloses how to make and use (enables) the claimed invention. The Examiner acknowledges that the specification discloses examples using one LPS (from *S. typhi*) and peptide for the protection against gram negative bacterial infection. However, gram negative bacterial infections encompasses infections caused by *Actinobacillus*, *Klebsiella*, *Streptobacillus*, *Vibrio*, *Pasteurella*, *Chlamydia*, *Bordetella*, *Campylobacter*, and *Mycoplasma* to name a few. The specification has not set forth evidence that one LPS (from *S. typhi*) and peptide can provide protection against any gram negative bacterial infection (see for example those bacteria set forth above). Applicants have set forth claims directed to the LPS being *H. influenzae*, or *N. meningitidis*, but there is no enablement set forth in the specification for these limitations. The previous Office Action has established that all trials of new therapies for sepsis conducted to date have failed to show efficacy and that there are no accurate predictions on the efficacy of novel therapeutic agents from in vitro studies alone (Bone, 1996 and Cross et al) .

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6. No claims are allowed.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

October 31, 2000


NITA MINNIFIELD
PRIMARY EXAMINER